

輸入食品系統性查核實施辦法

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第 一 條 本辦法依食品安全衛生管理法第三十五條第二項規定訂定之。

第 二 條 本辦法用詞，定義如下：

一、系統性查核：指針對輸出國(地)之食品衛生安全管理體系與政府機關監督措施之查核。

二、查核機關：指衛生福利部食品藥物管理署。

三、書面審查：指針對輸出國(地)政府機關提供輸出國(地)之食品衛生安全管理體系與政府機關監督措施之相關資料，進行審查。

四、實地查核：指查核機關派員至輸出國(地)，對其食品衛生安全管理體系，進行系統性查核。

第 三 條 實施系統性查核之產品範圍，如附表。

第 四 條 系統性查核應由輸出國(地)政府機關，向查核機關提出書面申請，由查核機關進行書面審查，必要時於書面審查後實地查核，經評估確認其食品衛生安全管理體系與政府機關監督措施與我國具等效性後，核定並同意輸出國(地)之申請輸入。

查核機關進行前項書面審查時，得視審查需求，要求輸出國(地)政府機關於指定期限內提供所需之文件。

依本辦法應實施系統性查核之產品，除有第七條之情形外，未經第一項之同意，不得依本法第三十條規定申請查驗。

第 五 條 完成系統性查核之輸出國(地)或依第七條免系統性查核者，有下列情形之一時，查核機關得再進行書面審查或實地查核，以確認輸出國(地)之管理體系與我國具等效性：

- 一、輸出國(地)食品衛生安全管理體系或政府機關監督措施有重大變革。
- 二、輸出國(地)境內發生重大食品衛生安全事件。
- 三、輸出國(地)輸至我國或其他國家之食品及其相關產品，經輸入查驗有嚴重違規情形。
- 四、依第七條免系統性查核或三年以上未執行實地查核，經查核機關認定有必要審查或查核。
- 五、其他經認定輸出國(地)食品及其相關產品有危害食品衛生安全之虞情形。

第 六 條 實地查核結果不符合時，得要求輸出國(地)限期將改善報告送查核機關審查，必要時，進行實地查核複查改善情形，並由輸出國(地)負擔複查費用。

第 七 條 依本辦法應實施系統性查核之產品，於本辦法施行前，已有輸入紀錄者，於原已輸入範圍內，得免申請系統性查核。

第 八 條 本辦法除另定施行日期者外，自發布日施行。

附表 實施系統性查核之產品範圍

類別	項目	備註
肉類產品	世界關務組織制定之國際商品統一分類代碼(HS code)為 02、0504、1601、1602 項下之產品。	<ol style="list-style-type: none"> 1. 左欄所列產品之輸入規定為 F01 或 F02 者。 2. 兩生類、爬蟲類、靈長類、水生哺乳動物類等其他非屬禽畜動物類及其產品，不在實施系統性查核之範圍內。
水產品	世界關務組織制定之國際商品統一分類代碼(HS code)為 03、1604、1605 項下之產品。	<ol style="list-style-type: none"> 1. 左欄所列產品之輸入規定為 F01 或 F02 者。 2. 本類別自一百零七年一月一日施行。
乳製品	世界關務組織制定之國際商品統一分類代碼(HS code)為 0401、0402、0403、0404、0405、0406、9806 項下之產品。	<ol style="list-style-type: none"> 1. 左欄所列產品之輸入規定為 F01 或 F02 者。 2. 本類別自一百零七年一月一日施行。
蛋品	世界關務組織制定之國際商品統一分類代碼(HS code)為 0407、0408、3502 項下之產品。	<ol style="list-style-type: none"> 1. 左欄所列產品之輸入規定為 B01 及 F01 者。 2. 本類別自一百零八年一月一日施行。
動物性油脂	世界關務組織制定之國際商品統一分類代碼(HS code)為 15 項下之產品。	<ol style="list-style-type: none"> 1. 左欄所列產品之輸入規定為 B01 及含 F01 者。 2. 本類別自一百零八年一月一日施行。
其他牛來源產	曾發生牛海綿狀腦病國家產製之非屬肉類產品之其	左欄所列產品屬以下項目，不在實施系統性查核之範圍內：

品	他牛來源食品。	<ol style="list-style-type: none">1. 不含蛋白質之牛油及其衍生物。2. 不含蛋白質或脂質之磷酸氫鈣。3. 牛原皮等。4. 從牛原皮製得之明膠與膠原蛋白。5. 牛來源原料源自非牛海綿狀腦病發生國家或我國已完成該原料系統性查核之牛海綿狀腦病國家，且檢附原料原產地證明文件以及產品衛生證明文件者。
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Regulations for Systematic Inspection of Imported Food

Promulgated on February 11, 2014

Amended on October 17, 2014

Amended on August 4, 2017

Amended on September 17, 2018

Article 1 These Regulations are established in accordance with the provisions of Paragraph 2 of Article 35 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “Act”).

Article 2 The terms used in these Regulations are defined as follows:

1. “Systematic inspection” means inspecting the food safety management system and the supervisory measures taken by the governments of the exporting country (territory).
2. “Inspection authority” means the Food and Drug Administration, Ministry of Health and Welfare.
3. “Document review” means reviewing the documentation relating to the food safety management system in the exporting country (territory) provided by the governmental authority of the exporting country (territory).
4. “On-site inspection” means the inspection authority designates inspectors to conduct the systematic inspection of the food safety management system in the exporting country (territory).

Article 3 The scope of products subject to systematic inspection is outlined in the attachment.

Article 4 To perform systematic inspection, the exporting country (territory) shall apply to the inspection authority with documents for approval of import of the product described in the above paragraph. Inspection authority shall conduct the documents review. If required, on-site inspection can be conducted following the document review. Only if the food safety management system of the exporting country (territory) is determined as equivalent based on the systematic inspection, the application of the exporting country (territory) will be approved.

If necessary, Inspection authority shall request the exporting country (territory) (territory) to provide the documents within the designated period when performing the pre-said document review.

Products which are subject to the scope of this regulation, are not conforming to the paragraph 1 of this Article shall not be applied for inspection unless are exempt according to Article 7.

Article 5 For any exporting country (territory) that has been systematically inspected and been approved to import or that is exempted from systematic inspection in accordance with the provisions of Article 7, in case of any of the following, the inspection authority may request document review or on-site inspection to confirm the equivalence of the management system of the exporting country (territory).

1. Significant changes of food safety management system or the supervisory measures of the exporting country (territory).
2. Occurrence of significant food sanitation and safety incidents in the exporting country (territory).
3. Significant violation of the food or related product from the exporting country (territory) found by the inspection authority or other importing country (territory).
4. Any exporting country (territory) that is exempted from systematic inspection in accordance with the provisions of Article 7 or that has been finished systematically inspected more than three years, deemed necessary to conduct documents review or on-site inspection by the inspection authority.
5. Food or related products which from the exporting country (territory) were determined as jeopardizing food safety.

Article 6 If the results of on-site inspection are non-compliant, the exporting country (territory) may be required to submit corrective actions, to the inspection authority for review before deadline. If required, on-site inspection might be performed again to verify the effectiveness of the

corrective actions and on-site inspection cost shall be borne by the exporting country (territory).

Article 7 Products, subjected to the scope of this regulation, had existed import records before promulgation of these Regulation might be exempted from the systematic inspection.

Article 8 These Regulations shall be implemented from the date of promulgation unless other specified.

Attachment Scope of Products Subject to Systematic Inspection

Type	Item	Remarks
Meat Products	Products listed in 02, 0504, 1601 and 1602 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	<ol style="list-style-type: none"> 1. Products on the left column subject to importation rules F01 or F02. 2. Products from amphibians, reptiles, primates, aquatic mammals are not subject to systematic inspection.
Fishery Products	Products listed in 03, 1604 and 1605 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	<ol style="list-style-type: none"> 1. Products on the left column subject to importation rules F01 or F02. 2. These products come into enforcement from January 1, 2018.
Dairy Products	Products listed in 0401, 0402, 0403, 0404, 0405, 0406 and 9806 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	<ol style="list-style-type: none"> 1. Products on the left column subject to importation rules F01 or F02. 2. These products come into enforcement from January 1, 2018.
Egg products	Products listed in 0407, 0408 and 3502 of the Harmonized System Codes (HS Codes) established by the World Customs	<ol style="list-style-type: none"> 1. Products on the left column subject to importation rules

	Organization.	<p>B01 and F01.</p> <p>2. These products come into enforcement from January 1, 2019.</p>
Animal oil products	Products listed in 15 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	<p>1. Products on the left column subject to importation rules B01 and included F01.</p> <p>2. These products come into enforcement from January 1, 2019.</p>
Products of bovine origin	Bovine derivatives food products, not classified as meat products, from BSE infected countries.	<p>Products on the left column belong to following foods are exempted:</p> <p>(1) Tallow and its derivatives without protein ;</p> <p>(2) Calcium hydrogen phosphate without protein ;</p> <p>(3) Bovine hide ;</p> <p>(4) Gelatin and collagen from bovine hide ;</p> <p>(5) Bovine derived products from non-BSE-infected</p>

		<p>countries or the BSE infected-country has been completed the systematic inspection with certificate of origin of the material and sanitation (health) certificate of the product.</p>
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